IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

CHARLES COLLINS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. 2:08-cv-438-MHT-PWG**
	)	
NOVARTIS PHARMACEUTICALS CORPORATION,	)	
	)	
	)	
Defendant.	)	

REPORT AND RECOMMENDATION

In April 2008, Charles Collins initiated this civil action with a complaint filed in the Circuit Court of Montgomery County, Alabama, in which he has alleged that Novartis Pharmaceuticals Corporation had breached a legal duty "... to ensure that the drugs it manufacture[d], market[ed] and [sold] are fit for the ordinary purpose for which such drugs are used...." (Doc. 3-1 at p.3).[1] Mr. Collins stated that in December 2001, he began to take the prescription medication Aredia to combat

[1] While the complaint does not mention the Uniform Commercial Code or the implied warranty of merchantability, the parties have more or less agreed that the complaint sounds in that statute. Alabama law imposes an implied warranty of merchantability upon the sale of a good, unless the parties contract to do something different. *Bagley v. Mazda Motor Corp*., 864 So.2d 301, 314–15 (Ala.2003) ("Unless specifically disclaimed, implied warranties are created upon the sale of goods."); *Cheminova Am. Corp. v. Corker*, 779 So. 2d 1175, 1180 (Ala. 2000) ("A sale of a product that is not fit for use as described violates the implied warranty of merchantability—that the product is fit for its intended purpose—an implied warranty that ... accompanies each sale by a merchant. § 7–2–314, Ala. Code 1975."). Specifically, Ala. Code section 7–2–314 provides that "[u]nless excluded or modified ([by] Section 7–2–316), a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Ala. Code § 7–2–314(1).

the effects of cancer. (*Id.*) The complaint alleged that as a result of his use of Aredia, Mr. Collins was "...caused to suffer from osteonecrosis of the upper and lower jaw...[producing] much pain as a consequence...." (*Id.* at p.4). Novartis removed the action to the United States District Court for the Middle District of Alabama. (Doc. 3). In the notice of removal, Novartis stated that "...a number of lawsuits involving similar claims and alleging similar damages have been filed in other federal courts... [and that] ... these cases have been or will be consolidated in a multi-district litigation... pending in the Middle District of Tennessee." (*Id.*) A conditional order was entered transferring this action and 77 more to the MDL. (Doc. 10). In March 2014, almost six years after Mr. Collins filed his law suit, the MDL court remanded 38 pending cases to the districts of original filing, including that of Mr. Collins, concluding that "...the purposes of the MDL [which included discovery] have been accomplished in these cases...." (Doc. 7334 MDL MDTN). In August 2014, the remanded action was reassigned to United States District Judge Myron H. Thompson. (Doc. 12). Judge Thompson directed the Defendant to file a motion for summary judgment and established a schedule for consideration of the motion. (Doc. 24). On October 17, Judge Thompson referred the matter to the Magistrate Judge for a recommendation. (Doc. 39); *see also* 28 U.S.C. § 636(b); Fed. R. Civ. P. 72; *United States v. Raddatz*, 447 U.S. 667, 100 (1980); *Jefferey S. v. State Bd. of Educ. of State of Georgia,* 896 F.2d 507 (11th Cir. 1990).

I. JURISDICTION

This court has jurisdiction over all civil actions in which the amount in controversy exceeds $75,000 and the action is between citizens of different states. 28 U.S.C. § 1332(a). In the notice of removal, Novartis alleged that it was a Delaware Corporation with New Jersey as the principle place of business and that Mr. Collins was a citizen of Alabama. (Doc. 3 at p.3). The parties have agreed that the damages sought exceed the jurisdictional threshold. (*Id.*) The requisite elements for diversity jurisdiction are present.

II. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 247 (1986). Once the moving party demonstrates the absence of a genuine issue of material fact, the non-moving party must "come forward with specific facts showing that there is a genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (quoting Fed. R. Civ. P. 56(e)). The Court must view the record and all factual inferences therefrom in the light most favorable to the non-moving party and decide whether "the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Allen v. Tyson Foods, Inc*., 121 F.3d 642, 646 (11th Cir. 1997) (quoting *Anderson*, 477 U.S. at 251–52)).

In opposing a motion for summary judgment, the non-moving party may not rely solely on the pleadings, but must show by affidavits, depositions, answers to interrogatories, and admissions that specific facts exist demonstrating a genuine issue for trial. *See* Fed. R. Civ. P. 56©, (e); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986). A mere "scintilla" of evidence supporting the opposing party's position will not suffice; instead, there must be a sufficient showing that the jury could reasonably find for that party. *Anderson*, 477 U.S. at 252; *see also Walker v. Darby*, 911 F.2d 1573, 1577 (11th Cir.1990).

The evidence tendered in support of or in opposition to summary disposition must be reducible to admissible form. "The general rule is that inadmissible hearsay cannot be considered on a motion for summary judgment." *Jones v. UPS Ground Freight*, 683 F.3d 1283, 1293 (11th Cir. 2012) (internal quotation marks omitted). "Nevertheless, a district court may consider a hearsay statement in passing on a motion for summary judgment if the statement could be reduced to

admissible evidence at trial or reduced to admissible form." *Id.* at 1293–94 (internal quotation marks omitted). Where there are two layers of hearsay, both layers must be excepted from the hearsay rule for the statement to be admissible. *See* Fed. R. Evid. 805 (providing that "[h]earsay within hearsay is not excluded by the rule against hearsay if each part of the combined statements conforms with an exception to the rule"); *see also United States v. Pendas–Martinez*, 845 F.2d 938, 942–43 (11th Cir. 1988) ("[E]ven if one level of double-hearsay statement was not hearsay under Rule 801(d)(1)(B), second level of hearsay was not excepted from rule and document was inadmissible" (citing *S. Stone Co. v. Singer*, 665 F.2d 698, 703 (5th Cir. Unit B Jan.1982)). And "[f]or the purposes of the hearsay-within-hearsay principle expressed in rule 805, 'non-hearsay' statements under rule 801(d) ... should be considered in analyzing a multiple-hearsay statement as the equivalent of a level of the combined statements 'that conforms with an exception to the hearsay rule.'" *United States v. Dotson*, 821 F.2d 1034, 1035 (5th Cir. 1987) (citing *S. Stone Co.*, 665 F.2d at 698); *accord Pendas–Martinez,* 845 F.2d at 943.

III. UNDISPUTED FACTS

In April 2001, Charles Collins was diagnosed with Stage III multiple myeloma, a cancer originating in bone marrow which can develop in any bone in the body. Mr. Collins' treating physician ordered chemotherapy and a bisphosphonate medication under the brand name of Aredia. Aredia was first approved by the FDA in 1991 for the treatment of the cancer and that approval remains in effect. Mr. Collins' oncologist testified that Aredia was the standard of care for patients presenting with multiple myeloma in 2001 and remained the standard when he was deposed on February 6, 2014. The drug is effective in preventing or delaying serious complications in multiple myeloma patients including fractures, spinal cord compression, and related pain. While not a cure, Aredia significantly enhances the quality of life for these patients. In Mr. Collins' case, he did not experience new fractures or new spinal compressions while using Aredia. According to his physician,

Mr. Collins benefitted from the treatment. At some point in 2003, Dr. Robert E. Marx, DDS published a "Letter to the Editor" in a journal for dental professionals alerting dentists to "...previously unrecognized and unreported serious adverse affects, [] in patients receiving ... Aredia [bisphosphonates] ... [and that] most patients present with painful exposed avascular bone in the mandible." (Doc. 26-10 at p.2). On September 24, 2003, Novartis notified the FDA that the company was revising the package insert to include information that "cases of osteonecrosis (primarily of the jaw) have been reported since market introduction [of Aredia]." (Doc. 27-12).[2]

In January 2004, Mr. Collins had teeth extracted. During a follow up visit on February 3, his dentist noticed a necrotic or dead bone. The dental records noted "multiple areas of exposed bone" in both the upper and lower jaw. (Doc. 27 at p. 12 (quoting Health Records [7673-0022] and [5262-0005])).[3] In May, Collins discontinued use of Aredia. On June 1, 2004, Dr. Holmes, a specialist, diagnosed Collins with "Osteonecrosis as a result of Aredia." (Doc. 28 at p. 2). The parties are in agreement that there is a condition known BRONJ or BRON (Bisphosphonate Related Osteonecrosis of the Jaw) which can result from (1) current or previous treatment with a bisphosphonate, (2) in patients with no history of radiation to the jaw, and (3) the exposed bone has persisted for more than eight weeks. (See Doc. 27 at p.12 n.44 and Doc. 28 at p. 7-8).

In the fall of 2004, Novartis again revised the package insert for Aredia to reflect that cases of osteonecrosis of the jaw (ONJ) had been associated with the use of the drug. A "Dear Doctor" letter concerning the revisions was mailed to 12,000 physicians and the letter was posted on an FDA

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[2] Later, as noted below, Novartis made changes to the insert and took additional steps to include warnings about osteonecrosis. The adequacy of such warnings is not relevant here. This is not a "failure to warn" action, which arises under a separate UCC provision. However, it may be that the fact there were warnings has some relevance the "dangerousness" inquiry.

[3] Mr. Collins does not take issue with the cited evidence in his opposition to the motion for summary judgment.

publically accessible website.[4] The insert and the Dear Doctor letter included a caution that a dental examination should be considered before treatment with Aredia and that a patient should avoid invasive dental procedures if possible. Even after he was made aware of the evidence of ONJ in some patients, Mr. Collins' oncologist testified that he would have prescribed Aredia for his patients.

> Q. And so the information you learned about ONJ did not stop you from prescribing intravenous bisphosphonates for your cancer patients; is that true?
>
> A. Yes. When the benefits are so overwhelming and the incidence of osteonecrosis is estimated to be 1.3 percent, like any other medication you use in medicine when the benefits outweigh the risks, we use it, you know, and we are aware of the potential problems.

(Doc. 27 at p. 5 (quoting Moraes deposition at p. 55:5-3)); (Doc. 27-1 at p.11).

IV. QUESTIONS PRESENTED AND DISCUSSION

Two related questions arise from the current motion and responsive papers. First, it must be decided whether, under Alabama law, a plaintiff in the posture of Mr. Collins may maintain an action for damages under the Alabama version of the Uniform Commercial Code alleging a breach of an implied warranty of merchantability for injuries sustained from the use of Aredia. If the answer to the first question is in the affirmative, the second question is whether Mr. Collins' discrete UCC claim is barred by the applicable statute of limitations.[5]

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[4] Mr. Collins' oncologist, Dr. Moraes, testified that in 2003 he was not aware of the warnings and did not communicate the information to Mr. Collins.

[5] Because the basis of the court's jurisdiction is diversity and because the claims at issue are state claims, it is Alabama substantive law, not federal substantive law, that governs this case. *Erie R.R. v. Tompkins,* 304 U.S. 64 (1938). This court must therefore make an educated guess of how the Alabama courts, and, in particular, the Alabama Supreme Court, would resolve these claims. *Blue Cross & Blue Shield of Ala., Inc. v. Nielsen,* 116 F.3d 1406, 1413 (11th Cir. 1997) ("The final arbiter of state law is the state supreme court, which is another way of saying that Alabama law is what the Alabama Supreme Court says it is."). Because there is no actual conflict between Alabama federal district courts on these questions and none between the Alabama courts and the federal courts, certification of either issue to the Alabama Supreme Court would be wasteful. The court is persuaded that existing sources of state law provide sufficient and significant guidance on this point,

THE UNIFORM COMMERCIAL CODE CLAIM
IMPLIED WARRANTY OF MERCHANTABILITY

A. The UCC Claim

Section 7-2-314 Alabama Code 1975 provides in pertinent part that in a commercial transaction there is "... (1) [unless modified], a warranty that the goods shall be merchantable [and that] (2) [g]oods [are] merchantable [if they] (c) [a]re fit for the ordinary purposes for which such goods are used...." The concept of merchantability developed in common law and courts began to adopt the term as a means of comparing the worthiness of goods to other like it in the marketplace. The intent was to determine if the subject goods would conform to what would customarily be expected of such products by the end users. These principles were codified in the Uniform Sales Act and later into the Uniform Commercial Code. *See generally* 18 REGULR 1979, *A Class-Action Lawsuit Against Aspartame Manufacturers* 2005-2006. The State of Alabama adopted the Uniform Commercial Code including the implied warranty of merchantability as codified in Alabama Code section 7-2-314. (1975). *Bodie v. Purdue Pharma Company,* 236 F. App'x 511, 2007 WL 1577964 at **8-**10 (11th Cir. 2007) ("These provisions in the Alabama Code mirror the Uniform Commercial Code's provisions on the implied warranty of merchantability.").[6] In general, a plaintiff can maintain an action predicated upon on a breach of the implied warranty of merchantability with

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and the question does not appear to be a close one for the reasons set forth *infra*. Under the circumstances, the undersigned's resolution of this question of Alabama law is not tantamount to an unnecessary *Erie* guess, but is instead appropriate. *See generally State Farm Mut. Auto. Ins. Co. v. Duckworth*, 648 F.3d 1216, 1224 (11th Cir. 2011) ("Where, as here, we find no [state] Supreme Court decision directly on point, we must anticipate how the [state] Supreme Court would decide this case.").

[6] *Bodie* appears in the Federal Appendix and is therefore "unpublished." When cited, it is not binding "'...but [] may be [] persuasive authority.' *See* 11th Cir. R. 36-2; *United States v. Rodriguez-Lopez*, 363 F.3d 1134, 1136 n.4 (11th Cir. 2004)." *Suntree Technologies, Inc. v. Ecosense International, Inc.*, 693 F.3d 1338, 1349 n.1 (11th Cir. 2012).

proof of (1) a warranty, (2) a breach, and (3) damages resulting from that breach. *Bodie*, 236 F. App'x at 522 (citing *Barrington Corporation v. Patrick Lumber Co.,Corp.,* 447 So.3d 785, 787 (Ala. Civ. App. 1984)).

B. The "Merger" of the UCC Claim Into the AEMLD

In 1984, the Eleventh Circuit Court of Appeals certified a question of Alabama law to the Alabama Supreme Court asking in pertinent part: "Does [state law] impose liability under a breach of implied warranty of merchantability on the manufacturer of an over the counter drug for injuries sustained from an uncommon reaction?" *Griggs v. Combe, Inc.*, 456 So.2d 790 (Ala. 1984). The Alabama court noted in *Griggs* that the record established that there had been no prior evidence that the product, a topical analgesic, induced Stevens-Johnson syndrome from which the plaintiff had suffered after use. Quoting and relying upon a survey of law from other jurisdictions presented in a UCC treatise the, Supreme Court wrote that:

> We agree with the above authorities that a product must adversely affect at least some significant number of persons before a question of 'merchantability' arises.

Griggs, 456 So. 2d at 793. The Alabama court did not attempt to explain under what circumstances a "question of 'merchantability' [would] arise[]" nor even what that question might be.

In 1986, two years after *Griggs*, the Alabama Supreme Court limited the scope of an action alleging a breach of the warranty of merchantability by explaining in *Shell v. Union Oil Company,* 489 So. 2d 569 (Ala. 1986) that "...a manufacturer's implied warranty was limited to '*commercial* fitness and suitability,' not 'the broader obligation to warrant against health hazards inherent in the use of the product....'" *Bodie*, 236 F. App'x at 523 (quoting *Shell*, 489 So. 2d at 572) (emphasis supplied in *Bodie*). The *Shell* court rejected the plaintiff's contention that because a product caused cancer, it could not be "fit" for the ordinary purpose for which the product was used because the product was inherently dangerous. The Alabama Supreme Court held instead that the UCC concerned itself only with the quality of a product by establishing whether it is fit for a particular use and not

with safety standards imposing strict liability on the seller of an unreasonably dangerous product that could cause physical harm. The *Shell* court specifically stated that the latter question was not properly addressed under the provisions of the UCC but rather when considering whether a given product was unreasonably dangerous, the question was to be analyzed in accord with tort law principles under the Alabama Extended Manufacturers' Liability Doctrine. The Supreme Court of Alabama observed that there was a "...clear distinction between causes of action arising under tort law and those under the UCC as adopted in Alabama." *Shell*, 489 So. 2d at 571. *Shell* made no reference to *Griggs* and did not identify a subset of UCC claims affecting a significant number of consumers as an exception to the blanket statement that the contention that a product was unreasonably dangerous would not be viable as a breach of the warranty of merchantability.

Shell appeared to settle the issue until the Alabama Supreme Court was again called upon to answer questions of Alabama law put to that Court by the Eleventh Circuit Court of Appeals in *Spain v. Brown & Williamson Tobacco, Corporation*, 872 So. 2d 101 (Ala. 2003).[7] The Eleventh Circuit had concluded that the plaintiff alleging an injury from smoking cigarettes "...does not state a claim for breach of implied warranty of merchantability" relying upon both *Shell* and *Yarbrough v. Sears, Roebuck & Co*, 628 So. 2d 478 (Ala. 1993).[8] While acknowledging the express language of *Shell* set

[7] The Eleventh Circuit "certified" five questions that did not implicate the issue presented here. The Court of Appeals "...also invite[d] [the Alabama Supreme Court] to tell us if the conclusions we have reached about... [4] state law issues are incorrect." The second of the invited issues was the appeals court's conclusion that "...the sale of cigarettes do not violate the implied warranty of merchantability...." The federal appeals court did not specifically ask if the UCC claim was merged with the AEMLD claim but did conclude that the complaint in *Spain* did not state a claim for Rule 12(b)(6) purposes.

[8] In *Yarbrough*, plaintiff filled a kerosene heater with gasoline and, when used, the heater caught fire, causing injury and property damage. The Alabama Supreme Court said of the plaintiff's AEMLD claims that "[i]n adopting the AEMLD the court defined a defective product as a product that is 'unreasonably dangerous, *i.e.*, not fit for its intended purpose.'" 628 So. 2d at 480-81. Later, the Court quoted *Shell* for the proposition that "whether the kerosene heater was unreasonably dangerous is not... properly addressed in a claim alleging a breach of warranty under the UCC...."

out above, the Alabama Court wrote that "...we cannot so limit the remedy for breach of an implied warranty." *Spain,* 872 So. 2d at 106. In cryptic fashion, the Alabama Court observed that while *Shell* "turns on the fact that the naphtha product was 'fit for the ordinary purposes for which such goods are used,' *Shell* does not stand for the proposition that a product 'unfit for the ordinary purposes for which such goods are used' cannot be unmerchantable." *Id.* at 108 (internal citations omitted). Citing *inter alia*, *Allen v. Delchamps, Inc.*, 624 So. 2d 1065 (Ala. 1993), the Court noted that under the AEMLD, a plaintiff must prove that he has suffered an injury by one who sold a product in a defective condition unreasonably dangerous to the ultimate user and that:

> *Similarly, the plaintiffs' implied warranty of merchantability claims requires that the plaintiffs show that the goods were unmerchantable or unfit for the ordinary purposes for which they are used ....* These two standards go 'hand in hand' at least in so far as food products, 'for it is apparent that a food product is defective or unreasonably dangerous if it is unfit for human consumption.

Id. at 109 (emphasis in *Spain*) (internal citations omitted). The Alabama court acknowledged that in defining "defect" as applied to UCC cases using terms borrowed from the AEMLD, it had "combined the doctrine of 'fitness for the ordinary purpose intended' of UCC law and the tort concept of 'unreasonably dangerous' in defining 'defect.'" *Id.* at 111. In the end, the court concluded that "the determination [of] whether there was a breach [of implied merchantability] requires a fact-intensive analysis." *Id.* at 108.

Mr. Collins contends that the *Spain* holding "...was perfectly clear: [that] a claim alleging breach of an implied warranty of merchantability is separate and distinct from an AEMLD claim and is viable to redress an injury caused by an unreasonably dangerous product.'" (Doc. 28 at p.6 (quoting *Spain*, 872 So. 2d at 111)).[9] Indeed, that certainly appeared to be the understanding of the

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Id. at 483.

[9] Novartis asserts that *Spain* is distinguishable because that case "...did not involve a prescription drug or device...." (Doc. 27 at p.11 n.42). That is true, of course, but *Spain* did not

Eleventh Circuit after the Alabama Supreme Court answered its questions. *See Spain v. Brown & Williamson Tobacco, Corp.*, 363 F.3d. 1183, 1198 (11th Cir. 2004) ("In our prior opinion in this case, we asked the Alabama Supreme Court to comment on our conclusion that Spain did not state a valid claim for breach of an implied warranty of merchantability. *Spain*, 230 F.3d at 1310–11. It did, and disagreed with our assessment of Alabama law.") The Eleventh Circuit concluded that, contrary its earlier view, a claim of a breach of the implied warranty of merchantability "... may not be dismissed [under Rule 12(b)(6)] for failure to state a claim under Alabama law." *Id.*[10]

It is of significance that the UCC/AEMLD question in *Spain* turned on what was essentially a question of the quantum of proof required to sustain the UCC claim. Unlike *Spain,* which involved a motion to dismiss without a developed factual record, *Shell* and *Yarbrough* were decided in light of Rule 56, on motions for summary judgment following discovery. Noting that the record in *Spain* did not contain any evidence that the "...the cigarettes smoked by [plaintiff] *were* 'fit for the ordinary purpose for which they are used' ... [the Alabama Supreme Court found] ... this case is factually distinguishable from *Shell* and *Yarbrough*." *Spain*, 872 So. 2d at 108-09 (emphasis in *Spain*). In

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involve food either and the Alabama Supreme court relied on a "food" case, *Allen v. Delchamps*, in concluding that a mechantability claim was not "so limited" as the Eleventh Circuit had thought. The actual distinction Norvartis seeks to assert is between products which have "utility other than consumption" (heaters, naphtha, and the company asserts hopefully prescription drugs) and those which don't (*e.g.* food). The Alabama Supreme Court did not make such a distinction although federal district courts have since done so. It is important to note that in *Allen,* the court found that because there were FDA concerns about the effects of the chemical used on the suspect lettuce to a "number of sulfite-sensitive people" significant enough to ban its use, the case was significantly different from *Griggs* and exempt from the "ultrasensitive" user test. While there no evidence of a ban here, the *Allen* court did distinguish between a single user reaction and the potential for many users to be adversely affected.

[10] While the Eleventh Circuit appeared convinced, district courts were less sure. *See e.g. Garrison v. Novartis Pharmaceuticals Corp.*, --- F. Supp. 2d ----, 2014 WL 2968510 at n.8 (M.D. Ala. 2014) (CJ Watkins) ("More specifically, Novartis asserts that AEMLD encompasses [plaintiff's] strict liability (Count I), breach of implied warranty (Count V), and defective manufacture claims (Count II) ... [defendant's] argument is supported by Alabama case law, and [plaintiffs] does not dispute this characterization of her claims.")

Bodie, discussed *supra*, the Eleventh Circuit panel concluded that plaintiff's allegation that the drug OxyContin was "not of merchantable quality" because it was "unsafe" and "unreasonably dangerous" would not sustain a cause of action under Alabama law for breach of implied warranty of merchantability when "the evidence suggest[ed] the OxyContin was, in fact, fit for its intended use as an analgesic treatment for chronic pain...." 236 F. App'x at p. *10.

It appears evident that federal courts have been required to address the residual consequences of *Spain* and *Shell* with greater frequency that the state courts. In *Barnhill v. Teva Pharmaceuticals USA, Inc.*, 819 F. Supp. 2d. 1254, 1264 (S.D. Ala. 2011), the plaintiff, allegedly injured from the use of a prescription antibiotic, argued that *Griggs* provided an exception to the general rule that Alabama courts do not recognize a cause of action for breach of implied warranty of merchantability for inherently dangerous products. The *Barnhill* plaintiff asserted that there was evidence of non-merchantability. Judge Charles Butler concluded that *Griggs* had indeed "...left the door slightly ajar to the possibility of a breach-of-implied-warranty claim if the product adversely affected 'a significant number of persons.'" Judge Butler noted that, like the bisphosphonates at issue here, there was evidence of adverse reactions and side effects associated with the use of the drug and that "[a]s an inherently dangerous product, [the antibiotic] is presumed to be merchantable, *i.e.* fit for its intended use." 819 F. Supp. 2d. at 1264. In other words, merely because a product may cause injury even when used as intended does not render the product unfit as that term applies to the commercial claim under the UCC. Judge Karon O. Bowdre explained the interplay between "fit" and "defect" this way:

> The *Shell* case established that where the evidence reflects that the product is fit for its intended purpose even though it contains inherent dangers the breach of warranty claim is subsumed and is not viable. However, under *Allen,* if evidence exists that the product was *not* fit for its intended purpose then the breach of warranty claim is viable separate and apart from the AEMLD claim.

Wilson v. Kidde Products Limited, 2012 WL 3542210 at *10 (N.D. Ala. 2012) (emphasis in original). In *Houston v. Bayer Healthcare Pharmaceuticals, Inc.*, 16 F. Supp. 3d. 1341 (N.D. Ala. 2014), Judge

William M. Acker concluded that the "crucial fact in [the] 'fact intensive analysis' is what the purpose of the product at issue is."[11] *Id.* at 1347. *Houston* is not markedly different from earlier federal cases despite Novartis' exuberant endorsement of its "careful[] reason[ing]." (Doc. 37 at p. 1).[12] At the core, *Houston* stands for the unremarkable proposition that if a product is fit for the intended purpose, for example in the treatment of debilitating symptoms of cancer, it does not become "unfit" solely because there are serious health consequences and dangers associated with its use.[13] Merely contending that use of a product imposes a significant risk of serious harm for some consumers says nothing about whether a product is fit for its intended purpose. *See In Re Trasylol Products Liability Litigation (MDL)*, 2010 WL 5140439 at *11-*13(S.D. Fla. 2010) (The MDL court analyzed Alabama law of implied warranty of merchantability in light of plaintiff's claim that Trasylol was commercially unfit because it caused renal failure. The court granted summary judgment in the absence of proof that "...Trasylol did not successfully reduce perioperative bleeding"

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[11] Judge Acker concluded that if the product was merely to be consumed such as cigarettes and food, there is room for a UCC claim because it is the act of consumption not use that makes the product dangerous. If, however, according to *Houston,* there is some other purpose such as treating the symptoms of disease, the implied warranty "... applies only to that purpose and any unreasonable danger of the product must be addressed by the AMELD...." This approach is not inconsistent with Alabama law. In cases decided before *Allen*, the Alabama courts had concluded that a food product was defective or unmerchantable if it was unfit for human consumption. *See Cain v. Sheraton Perimeter Park S. Hotel*, 592 So. 2d 218, 220 (Ala. 1991) and *Ex Parte Morrison's Cafeteria of Montgomery*, 431 So. 3d 975, 977 (Ala. 1983). The "consumption" analysis of *Houston* is also consistent with earlier federal cases relying on the "purpose" test for UCC merchantability claims. *McClain v. Metabolife International, Inc.*, 193 F. Supp. 2d 1252 (N.D. Ala. 2002) (Buttram, J.) ("Plaintiffs do not contend that Metabolife 356 was not fit for the purpose for which it was sold, *i.e.* weight loss... [but that] [the product] is unreasonably dangerous []...Plaintiffs' warranty claims are not so much 'subsumed' as they are simply inapposite and non responsive to Plaintiffs' alleged injuries and claims.").

[12] "Judge Acker slammed shut the door on any theoretical opening for an implied warranty claim in a prescription drug case in Alabama ...in [*Houston*]." (Doc. 37 at p. 1).

[13] There may be duties to warn and the like as a result of these dangers but this case is not about warnings; it is about merchantability.

in patients undergoing cardiac surgery.) As noted earlier, if the product does what it is supposed to, that product is presumed merchantable even if there are also substantial risks connected with the use of that product.

While Novartis contends that the AEMLD subsumes or forecloses a UCC action except for an acknowledged "theoretical" possibility, which it argues was demolished by Judge Acker in *Houston,* the defendant does not seem to acknowledge that an action that is possible in theory cannot also be foreclosed as a matter of law. Judge Acker did not hold that all UCC claims are subsumed; he merely held that one subspecies of such claims must be brought under tort law. There is no other case that explicitly adopts Judge Acker's "purpose other than consumption" reasoning.[14] Alabama law remains clear, however, that in almost every case, a claim of an alleged breach of implied warranty of merchantability under the UCC is subsumed by AEMLD except for a theoretical possibility which has only been applied on summary judgment to the consumption of food products and never to prescription drugs or products with another consumer use beyond consumption. In *Allen*, the Alabama Supreme Court referred to *Griggs* primarily by exempting the claim from the single sensitive user analysis.

Like the Alabama courts actually addressing a UCC claim, the federal courts assessing the merchantability claim have consistently held that the plaintiff must demonstrate that the product was not "fit" for the intended purpose and the mere presence of harmful consequences which may result from appropriate use will not render a product unfit for the commercial purposes of the Uniform Commercial Code. These courts have concluded that the plaintiff's evidence failed to establish as a matter of law that the UCC claim was in that extraordinarily limited category of such claims purportedly recognized in *Griggs* and, to even a lesser extent, *Allen.*

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[14] That is not to say that the reasoning is in any way flawed. It is not. *Houston* represents the clearest approach extant to explain the state of the law. As an *Erie* guess, it is certainly a good one.

C. Analysis

The parties have labored to put forth their reasonable positions within the framework of an inchoate development of the defining principles. Alabama state courts have never allowed a UCC claim under the so called *Griggs* exception and the only case that authorized a merchantability action did so after concluding that *Griggs* did not apply.[15] Likewise, federal courts have either required proof from the plaintiff that the product did not work as intended or assessed the evidence of harm in comparison to the benefits from the product. This approach certainly seems consistent with even the most plaintiff oriented view of *Griggs*. The question actually answered in *Griggs* was whether a single ultra-sensitive user could sustain a UCC claim. The Alabama court said no and went on to say that it would not even consider the question unless there is proof that a substantial number of people were harmed. Should a plaintiff develop and offer such proof, the nature of which was not defined, it would be only at that point would the court undertake to decide whether a discrete UCC claim had arisen. This approach is the same taken by all federal district courts which, like the Alabama courts have unanimously rejected merchantability claims for products other than produce.

The only evidence Mr. Collins has offered to satisfy his self-described *Griggs* burden is found at p.5 of his response to the Defendant's motion for summary judgment where he states:

> Unlike the Griggs and Teva case [sic], here there is ample evidence that osteonecrosis arising out of bisphosphonate use has effected [sic] a significant amount of people. For example by 2010, over 600 lawsuits had been consolidated in the MDL related to this issue. Doc. 25-36 at p. 3. The position paper of the American Association of Oral and Maxillofacial Surgeons estimated rates of incidence of Bisphosphonate-related osteonecrosis of the jaw (BRON) from .8% to a whopping 12% of prescribed patients. (Doc. 27, ex 16 at 3).

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[15] *Allen* observed that the single sensitive user test did not bar the claim and did not address the potential number of persons harmed because the FDA had already banned the use of the chemical which adulterated Delchamps' lettuce. It was the banned chemical, not the product, which caused the harm. The chemical made this particular lettuce harmful. Lettuce generally as a food source was not harmful. The latter was "fit" for human consumption; the former was not. Untainted lettuce functioned as it should. The tainted lettuce did not.

(Doc. 28 at p. 5). The position paper referred to merely states :

> The clinical efficacy of IV bisphosphonates for the treatment of hypercalcemia and bone metastases is well established. Currently available published incidences data for BRON are limited to retrospective studies with limited sample size. Based on these studies, estimates of the cumulative incidence of BRON range from 0.8% -12%.[16]

(Doc. 27-16 at p. 3 (emphasis added)).

Additionally, in affirming that he would continue to prescribe Aredia, Mr. Collins' oncologist testified in 2014 that the incidence of BRON was "1.3 percent and [] when the benefits outweigh the risk, like any other medicine, we use it." (Doc. 28-3 at p. 3; Moraes Deposition at 55). Assuming without deciding that Mr. Collins could produce admissible evidence stating precisely what he has stated, the evidence says nothing at all about the merchantability of Aredia.[17] The evidence merely

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[16] Two additional points concerning the position paper are important. First, the estimates of incidence statement is followed by a footnote directing the reader to notes 34-42 which, in turn, merely list the titles of other reports, letters, and articles. There is no underlying data at all. In addition to the double hearsay nature of this evidence, it is crucially important that these notes do not contain any hint as to sample size, methodology or anything else. It is impossible to determine from the cited paragraph or the footnotes supporting it whether the 12% figure is whopping or not because there is no explanation in either as to what was compared to what. Second, the paragraph written in 2006 predicts the incidence of BRON occurring in IV treatment cases would rise but Mr. Collins does not identify additional evidence in any form after the date of publication. The is no authority cited for the legal proposition that the number of lawsuits filed has probative value on this question.

[17] The general rule is that inadmissible hearsay cannot defeat a motion for summary judgment where there is no indication that it is reducible to a form that would be admissible at trial. *Wyant v. Burlington N. Santa Fe R.R., R.C.*, 210 F. Supp. 2d 1263 (N.D. Ala. 2002) (quoting *Pritchard v. S. Co. Servs.,* 92 F.3d 1130, 1135, *amended in part on rehearing*, 102 F.3d 1118 (11th Cir. 1996), *cert. denied*, 520 U.S. 1274 (1997)). There is no showing here that the report or the underlying papers would be reducible to an admissible form. Even if they could be, the evidence does not establish an issue of material fact. Mr. Collins is required to produce "sufficient [favorable] evidence" which would be admissible at trial supporting his claim(s) for relief. *Anderson*, 477 U.S. at 249; Fed. R. Civ. P. 56(e). "If the evidence [on which the nonmoving party relies] is merely colorable ... or is not significantly probative ... summary judgment may be granted." *Id.* at 249–250 (internal citations omitted). "A mere 'scintilla' of evidence supporting the opposing party's position will not suffice; there must be enough of a showing that the [trier of fact] could reasonably find for that party." *Walker v. Darby*, 911 F.2d 1573, 1576–1577 (11th Cir. 1990) (citing *Anderson*, 477

demonstrates that there are potential adverse consequences associated with the use of the drug. That is not enough. What must be shown is that Aredia is not fit for its intended purpose. In *Allen*, the lettuce was not fit for the intended purpose of human consumption because it was treated with a banned chemical. Here, the evidence is over whelming that the drug is fit for the purpose despite the fact that there are health hazzard to some patients associated with the use of Aredia. As. Mr. Collins' doctor stated in response to the specific question, the benefits of Aredia continue even to this day to outweigh the risk.

> Q. And if you knew in May 2001 everything you know today about the possible risk of ONJ associated with Aredia, would you still have prescribed Aredia for Mr. Collins?
>
> A. Yes. Like we do nowadays, I would have been more proactive. Like I said, I would have made sure he had seen a good dentist that has experience dealing with that, you know, early on before even placing him on therapy... more proactive, you know, about it because we know much more than we knew back then to try to detect early. *But still, the benefits outweigh the risks and each and every doctor in the country uses it nowadays, you know.*

(Doc. 27-1 at pp. 15-16) (emphasis added).

The end result of all this is that Mr. Collins cannot establish that Aredia is not fit for the intended purpose. The question of proof in this context is not merely whether there is sufficient evidence for a jury to decide the question but the more fundamental one of whether Mr. Collins can establish as a matter of law that his claim is shrouded in ethereal mist of a *Griggs* UCC cause of action. The Alabama courts have never permitted such a claim to advance. The persuasive authority of *Bodie, Houston, Wilson, In Re Trasylol, Barnhill,* and *McClain* are indistinguishable from any Alabama case decided on the on the relevant question. A drug product is fit for the purpose intended

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U.S. 242). Conclusory allegations based on subjective beliefs are likewise insufficient to create a genuine issue of material fact and, therefore, do not suffice to oppose a motion for summary judgment. *Waddell v. Valley Forge Dental Associates, Inc*., 276 F.3d 1275, 1279 (11th Cir. 2001); *Holifield v. Reno,* 115 F.3d 1555, 1564 n.6 (11th Cir.1997).

even when there are serious health consequences for some users when the product is shown to achieve its commercial purpose. This presumption of merchantability cannot be overcome merely by demonstrating that there are risks associated with the use by a particular patient or group of patients. As Judge Acker noted in *Houston*, this legal standard does not mean that manufacturers are free to produce products that cause harm and remain unaccountable. Alabama law provides a complete remedy for such occurrences under the AEMLD. As the *Griggs* court predicted, the question of merchantability does not arise under factual allegations such as those presented here.

Mr. Collins has produced no admissible evidence to suggest the Aredia is not fit for its commercial purpose as required to maintain a UCC claim nor has he suggested how the material submitted might be reducible to admissible form. More importantly, however, even if the material submitted were considered in its entirety, the "facts" asserted do not rise to the level required by law to implicate the remedy under the UCC for a breach of implied warranty of merchantability.

THE STATUTE OF LIMITATIONS

Under controlling authority, Mr. Collins' claim is barred by the applicable statute of limitations. The fundamental issue of when a claim accrues for the purposes of time limitations on a cause of action is not unsettled under Alabama law. In 2008, the Alabama Supreme Court directly addressed the question of when the statute of limitations begins to run in cases in which the plaintiff had been exposed to a toxic[18] substance that later gave rise to an injury. *Griffin v. Unocal Corp.*, 990 So. 2d 291 (Ala. 2008). In *Griffin*, the Court expressly adopted the reasoning of Justice Harwood's

[18] Novartis asserts that *Garrett,* cited by Mr. Collins, is "entirely irrelevant" to "a pharmaceutical case" because it involved the date upon which an exposure to hazardous chemicals occurred. (Doc. 38 at p.6). Why this is so is not readily apparent. The issue in *Garrett* is accrual not merely exposure.

dissent in *Cline v. Ashland, Inc.*, 970 So. 2d 755, 761 (Ala. 2007).[19] Justice Harwood's opinion interpreted the statute of limitations in Alabama and, more specifically, "[t]he proper construction of the term 'accrued'" found in Alabama Code section 6-2-30. *Griffin*, 990 So. 2d at 310.

In Alabama, "[a]ll civil actions must be commenced after the cause of action has accrued within the period prescribed in this article and not afterwards, unless otherwise specifically provided for in this code." Ala. Code. § 6-2-30. The *Griffin* court found, in adopting Justice Harwood's reasoning, that "a cause of action accrues only when there has occurred a manifest, present injury." *Griffin*, 990 So. 2d at 310. An injury is manifest when there are "observable signs or symptoms ... the existence of which is medically identifiable." *Id.* The opinion repeatedly emphasized that the injury need not even be obvious to the injured party. *Id.* at 310-11. In fact, the court rejected the position now asserted by Mr. Collins by stating that: "'Manifest' in this sense does not mean that the injured person must be personally aware of the injury or *must know its cause or origin*." *Id.* at 310 (emphasis added). *Accord Utilities Bd. Of City of Opp v. Shuler Bros., Inc.*, 138 So. 3d 287, 293 (Ala. 2013). Instead, "[a] cause of action accrues at the time the complained-of action first gives rise to injury, even if the full extent of the injury is not apparently at the time." *Martin v. Cash Express, Inc.*, 60 So. 3d 236, 248 (Ala. 2010) (quoting *Van Hoof v. Van Hoof*, 997 So. 2d 278, 296 (Ala. 2007)).

Plaintiff argues that a claim does not accrue until a plaintiff is "entitled to maintain a cause of action" and that he could not have done so until a diagnosis of BRON was made in June. (Doc. 28 at p. 7). He relies on *Garrett v. Ratheon Company, Incorporated*, 368 So. 2d 516 (Ala. 1979), and

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[19] Although *Griffin* is applicable only prospectively, 990 So. 2d at 293, *see also, e.g.*, *Jerkins v. Lincoln Elec. Co.*, 103 So. 3d 1, 5 (Ala. 2011), the decision was published on January 25, 2008, just a few months before Plaintiff filed his complaint, and is clearly governing law in this case.

Alabama Code section 7-2-725. Neither supports his position. Alabama Code section 7-2-725 specifically defines accrual of a cause of action for breach of warranty as occurring "when the breach occurs, *regardless of the aggrieved party's lack of knowledge of the breach*... however, a cause of action for damages for injury to the person in the case of consumer goods shall accrue *when the injury occurs*." Ala. Code § 7-2-725(2) (emphasis added).

Plaintiff fares no better in light of *Garrett*, which he asserts supports a finding that his claims are timely. (Doc. 28 at p.7). As an prefatory matter, *Garrett* - also a toxic tort action - was explicitly overruled by *Griffin*. 990 So. 2d at 293. And although *Garrett* does stand for the general rule that a claim accrues when a party is entitled to maintain an action, it also holds that the statute of limitations begins to run "whether or not the full amount of damages is apparent..." and even if the plaintiff is "ignoran[t] of the tort or injury...." *Garrett*, 368 So. 2d at 519. *Accord Chaney v. Ala West-AL, LLC*, 22 So. 3d 488, 496-97 (Ala. 2008) (quoting *Payne v. Alabama Cemetery Ass'n*, 413 So. 2d 1067, 1071-72 (Ala. 1982)). In fact, the court found in *Garrett* that the plaintiff sustained injuries when he was last exposed to radiation, *id.* at 520, well before his injury manifested and a much harsher result than that required by *Griffin*.[20]

According to the complaint, the following injuries were present in January 2004: "osteonecrosis of the upper and lower jaw," "fracture of the right lower jaw," and pain related to those problems. (Doc. 3-1 at pp. 4-5). On February 3, 2004, at a follow-up visit, Plaintiff's dentist noted multiple areas of exposed, necrotic bone. (Doc. 27 at p. 12). The presence of these injuries, even without discovery of the underlying cause, is sufficient under Alabama law to manifest an injury.

[20] Plaintiff also makes a fleeting reference to continued prescription of Aredia in May 2004. Since the injury had already manifested itself several months earlier, the continued use of a drug that was known to cause such injuries will not prolong the viability of Plaintiff's claim.

Whether or not Plaintiff was aware of the exact cause or diagnosis, these were "observable signs and symptoms" that were "medically identifiable." Indeed, they were identified shortly thereafter as "osteonecrosis as a result of Aredia." (Doc. 28 at p. 2). There is no question that Plaintiff was aware of the presence of his injuries because he visited a specialist to seek diagnosis.

As Defendant correctly noted, Alabama has rejected a discovery rule outside of the fraud context legislated in Alabama Code section 6-2-3. *Shuler Bros.*, 138 So. 3d at 293. To find that the cause of an injury must be diagnosed before the statute of limitations begins to run would be tantamount to creating a discovery rule in this context. *See Griffin*, 990 So. 2d at 311 ("Thus, I reject the notion that our prior and present requirement of a 'manifest,' present injury means that the injury must be obvious to and known by the injured party. That would simply represent the creation of a type of discovery rule."). The creation of such a rule is outside the purview of the courts and lies instead with the Alabama legislature. *Id.*

Plaintiff cites *Scharff v. Wyeth*, 2011 WL 3320501 (M.D. Ala. 2011) for the proposition that a claim accrues on the date of diagnosis. (Doc. 28 at p.8). However, this case is not helpful to Plaintiff because the *Scharff* court expressly did not resolve the question of when the claim accrued, reasoning instead that "...it is unnecessary to choose between the two... dates. Viewing the facts in the light most favorable to [the plaintiff], the court assumes, *without deciding*, that her claim accrued on [the date she was notified of lab results diagnosing her cancer]." *Scharff*, 2011 WL 3320501 at *10 (emphasis added). The court made no finding on the accrual date of the plaintiff's claim and the case therefore is not informative to the question before this court.

This rule is not limited to toxic substances cases. For example, *Collins v. Davol, Incorporated* presents an analogous situation involving a latent physical injury. No. 3:14-cv-01392, 2014 WL

5661631 (N.D. Ala. Nov. 4, 2014). In *Collins*, the plaintiff suffered a hernia that was repaired. *Id.* at *2. The mesh used in the repair turned out to be defective and he suffered a recurrent hernia as a result. *Id.* Although the recurrent hernia was diagnosed in April of 2012, the defective mesh was not found to be the cause until August of that year. *Id.* The *Collins* court found the plaintiff's claim to have accrued on the date the recurrent hernia was diagnosed in April rather than when he later learned of the mesh's defect. *Id.* at *5. In making this determination, the court focused on the date of the injury and found the length of time it took to determine the cause immaterial. *Id.*

Likewise, a negligence claim was deemed to have expired in *Franklin v. Mitchell*. 87 So. 3d 573 (Ala. Civ. App. 2011). There, the plaintiffs' floor began to sag several years after their house was built. *Id.* at 575. They were unable to pinpoint the cause of the sagging for over a year, when they engaged the services of a home inspector, who determined that several air conditioning boots were allowing moisture to condense on the wood in the floors. *Id.* The plaintiffs argued that they "could not have known that they had an injury that was actionable" until they knew the cause of the sagging floors. *Id.* at 579. However, the court found that the statute of limitations began to run when the plaintiffs first noticed the sagging floors in April - that is, when the damage occurred, not when the cause was determined. *Id.*

Regardless of the context, the law regarding the accrual of a claim in Alabama is consistent and settled. Based on that law, Plaintiff's claim accrued no later than February 3, 2004, even if no label was affixed to his injuries until June. The statute of limitations ran on February 3, 2008 at the latest, and this case was not timely filed.

Finally, Mr. Collins argues that this court has the authority and duty to adopt a cross jurisdictional tolling provision applicable to federal litigation following the Supreme Court's holding

in *Crown, Cork &Seal Co. v. Parker,* 462 U.S. 345 (1983). Mr. Collins observes that the Alabama Supreme Court also adopted a class action tolling provision for Alabama cases in *White v. Sims,* 470 So.2d 1191 (Ala. 1985). Mr. Collins describes himself as a putative member of a class action filed in the Middle District of Tennessee in 2005. The class certification in that action was denied in 2007. He contends that if the cross jurisdictional tolling provision rule was applied to his claim, the claim would have been timely.

In 2005, Judge Harold Albritton of the Middle District of Alabama addressed the interplay between federal and state courts actions in light of Alabama pronouncements regarding tolling noting that federal courts generally, when examining "cross-jurisdictional tolling," had proved to be reluctant to expand the scope and availability of a state's equitable tolling power.[21] Judge Albritton distinguished Alabama's willingness to equitably toll actions filed in its own courts and tolling based upon filings in another state or federal court. He concluded that absent binding support for the proposition that Alabama state law claims are equitably tolled by an earlier federal action, such tolling is unavailable. In 2008, Judge William Acker, referring to *White,* also found that because *White* sought to establish a statewide class, the expansive language in the opinion was directed only to state class actions.[22] *Love v. Wyeth*, 569 F. Supp. 2d 1228 (N.D. Ala. 2008). It is one thing for a federal court to assess differing factual constructs in light of legal principles previously espoused by the Alabama Supreme Court and yet another for a federal court to effect a substantive change in Alabama

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[21] Mr. Collins correctly observes that four states have adopted such a rule while also conceding that four states have declined to do. It is that infringement on the State's prerogative that motivates federal court reluctance.

[22] This view is consistent with the *White* Court's recognition that what was to be protected through the tolling provision was the aspirational goals of Rule 23, Alabama Rules of Civil Procedure.

law predicated upon dicta in a case addressing a separate issue altogether. *Blue Cross & Blue Shield of Ala., Inc. v. Nielsen*, 116 F.3d 1406, 1413 (11th Cir.1997) ("The final arbiter of state law is the state supreme court, which is another way of saying that Alabama law is what the Alabama Supreme Court says it is."). A federal court can decide an issue of state law only when it may do so without resorting to "making unnecessary Erie 'guesses.'" *CSX Transp., Inc. v. City of Garden City*, 325 F.3d 1236, 1239 (11th Cir. 2003) (quoting *Mosher v. Speedstar Div. of AMCA Int'l, Inc.*, 52 F.3d 913, 916–17 (11th Cir. 1995)). Here the law is not such that a new rule may issue. This court must decline to unilaterally enact a substantive change is Alabama law.

V. CONCLUSION

Accordingly, for the reasons as stated, it is the **RECOMMENDATION** of the Magistrate Judge that Defendant's motion for summary judgment (Doc. 26) is due to be **GRANTED**.

Finally, it is **ORDERED** that the parties shall file any objections to this recommendation on or before **January 28, 2015**. Any objections filed must specifically identify the findings in the Magistrate Judge's recommendation to which the party objects. Frivolous, conclusive or general objections will not be considered by the District Court. The parties are advised that this recommendation is not a final order of the court and, therefore, it is not appealable.

Failure to file written objections to the proposed findings and recommendations in the Magistrate Judge's report shall bar the party from a *de novo* determination by the District Court of issues covered in the report and shall bar the party from attacking on appeal factual findings in the report accepted or adopted by the District Court except upon grounds of plain error or manifest injustice. *See Nettles v. Wainwright*, 677 F.2d 404 (5th Cir. 1982).

DONE and **ORDERED** this 14th day of January, 2015.

/s/ Paul W. Greene
United States Magistrate Judge